United States Court of Appeals
for the Sixth Circuit

ETHEL CUPEK, et al.,
Plaintiffs-Appellants,

v. No. 04-3201.

MEDTRONIC, INC.,
Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Ohio at Cincinnati.
No. 97-00105—Sandra S. Beckwith, Chief District Judge.

Argued: March 10, 2005
Decided and Filed: April 21, 2005

Before: KENNEDY, MOORE, and SUTTON, Circuit Judges

OPINION

KENNEDY, Circuit Judge. Plaintiffs appeal the district court's denial of leave to amend their complaint in this product liability action and the grant of summary judgment to Defendant Medtronic, Inc. based on this court's earlier decision in *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir.2000), dismissing similar claims. We affirm the district court.

BACKGROUND

Plaintiffs collectively sued Defendant alleging defects in Defendant's pacemaker leads implanted in them or their spouses. Their cases were consolidated with *Kemp v.*

Medtronic, Inc., No. C-1-97-103, 1999 (N.D. Ohio June 27, 1997) for the purposes of discovery. After all cases were consolidated in the Southern District of Ohio and after the district court denied Plaintiffs class certification, consolidation for trial, and permissive joinder, the parties agreed to administratively close all claims save *Kemp*. That case was fully litigated and appealed. *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir.2000) (denying the bulk of Plaintiffs' claims due to federal preemption), *rehearing and rehearing en banc denied*, No. 99-3720, 2001 WL 91119 (6th Cir. Jan. 26, 2001) (unpublished), *and cert. denied*, 534 U.S. 818 (2001).

After resolution of the *Kemp* case, Plaintiffs filed a motion to reinstate their actions and file an amended complaint to present new causes of action that federal law does not preempt, and to raise arguments that are distinguishable from the arguments made in *Kemp*. Defendant did not oppose reopening the case and moved the court to grant it summary judgment pursuant to a motion it had earlier filed at the conclusion of the *Kemp* appeal.

Plaintiffs' proposed amended complaint comprised eight counts. Counts I and II alleged post-sale "failure to warn" and post-sale "failure to recall" claims against Defendant based on "information learned after FDA review of the Model 4004 4004M PMA Supplement Applications."[1] Count III alleged that Defendant failed "to [c]omply with [f]ederal [r]equirements [c]onsistent with [s]tate [r]equirements." ("Medtronic failed to comply with applicable CFR regulations in its Model 4004 4004M PMA Supplement applications.").

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[1] Paragraphs 41 and 48 of these two counts read: "These duties are independent of any obligation a manufacturer may have to comply with applicable federal regulations."

Count IV alleged Defendant's "Negligence Per Se" in its "failure to comply with the [Food and Drug Administrations's (FDA)] conditions of approval." Counts V through VIII reasserted claims originally plead by Plaintiffs in their original complaint with greater factual specificity.

The district court disposed of Plaintiffs' motion to amend in three separate opinions and then granted summary judgment to Defendant in a final opinion. In the first opinion, issued on December 10, 2001, the district court found that counts V through VIII were directly precluded by *Kemp*. It also found that count IV was preempted because it was, in essence, a disguised fraud on the FDA claim. The district court found that federal law preempts such claims (citing *Kemp* and *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341, 348 (2001)). The district court additionally found that counts I and II were preempted by federal law because they would impose state requirements "different from" or "in addition to" federal requirements, thus making them futile claims. The court did, however, find that federal law did not preclude Plaintiffs' proposed count III. It granted Plaintiffs ten days to file an amended complaint alleging that sole claim.

Plaintiffs failed to file the required amended complaint within the allotted time and, instead, on January 14, 2002, requested that the court reconsider its decision. Before the court ruled on that motion, the parties requested a stay to allow them to engage in settlement discussions. The court granted the stay. After lifting the stay, on November 11, 2002, the district court denied Plaintiffs' request to reconsider its earlier decision. On December 13, 2002, Plaintiffs then requested leave to amend their complaint to allege the claim the court had previously allowed.

In its third opinion, filed on September 10, 2003, the district court denied Plaintiffs leave to amend their complaint, as previously allowed, holding that justice did not require granting Plaintiffs leave at that time, because of the opportunities given them to amend their complaint in a more timely fashion. The district court also expressed concern that Defendant would be unduly prejudiced were it to grant Plaintiffs leave to amend in view of how much time had elapsed since Plaintiffs filed their original complaint. The district court also directed Plaintiffs to show cause why it should not grant Defendant's motion for summary judgment. Finally, on January 13, 2004, after Plaintiffs filed a response to the show cause order, the district court granted summary judgment to Defendant on the remaining claims. This appeal followed.

On appeal, Plaintiffs allege three errors. First, Plaintiffs claim that the district court erred in denying them leave to amend their complaint to allege that Defendant was negligent per-se in failing to comply with the FDA's conditions of approval (count IV of the proposed amended complaint). Second, Plaintiffs allege that the district court erred in denying them leave to amend their complaint to assert Defendant's post-sale failure to warn and post-sale failure to recall claims (counts I and II of the amended complaint). Finally, Plaintiffs request that this court revisit its holdings in *Kemp* (and consequently reverse the district court's denial of leave to amend for counts V through VIII). Plaintiffs did not appeal the district court's denial of leave to amend count III of the proposed amended complaint.

ANALYSIS

We review de novo the district court's determination that granting Plaintiffs leave to amend would be futile. *See*

Ziegler v. IBP Hog Market, 249 F.3d 509, 518 (6th Cir.2001). We do not find error in the district court's decision. Granting leave to amend on count IV would be futile because that count is a disguised fraud on the FDA claim. The Supreme Court and this court held that federal law preempted such claims. *See Buckman,* 531 U.S. at 347-48 (explaining that the usual presumption against preemption does not apply where the field of law is inherently federal and stating that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"); *id.* at 349 n. 4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions: '[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.") (quoting 21 U.S.C. § 337(a)); *Kemp,* 231 F.3d at 236.

Federal law also preempts proposed amended counts I and II because those counts would impose state requirements "different from" or "in addition to" the federal requirement. *See* 21 U.S.C. § 360k(a) ("no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."). As recognized in *Kemp,* the FDA requires continuous updates as part of the pre-market approval (PMA) application and supplement process. *Kemp,* 231 F.3d at 221-22. These updating requirements specifically address warnings and recalls associated with medical devices. *See* 21 U.S.C. § 360h(a) (giving the Secretary of Health and Human

Services the authority to issue or withhold warnings concerning medical devices based on the Secretary's assessment of the risks); *id.* § 360(e)(1) (giving the Secretary authority to order manufac-turers to cease distributing devices upon a finding they could cause "serious, adverse health consequences or death"); *id.* § 360h(e)(2)(a) (giving the Secretary authority to issue recall orders); 21 C.F.R. § 803.50 (requiring device manufacturers to report adverse medical device events to the FDA); *id.* § 810.10 (giving the FDA discretion to determine if a recall is necessary and to decide to delay public notification to avert health risks). Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the PMA supplement process would constitute state requirements "different from" or "in addition to" the requirements of the federal PMA application and supplement process. *See* 21 U.S.C. 360k(a); *see also Kemp,* 231 F.3d at 235. Such requirements would, therefore, not "parallel federal safety requirements ...." *Buckman,* 531 U.S. at 353.[2] Plaintiffs' proposed amended claims themselves undermine their preemption arguments, because those claims assert that Defendant has duties "independent of any obligations ... to comply with applicable federal regulations." Such independent duties are, at the very least, "in addition to" federal requirements, and may very well be "different from" federal requirements. Thus, federal law preempts proposed amended counts I and II because those counts would require Defendant to comply with state requirements "different from"

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[2]There appears to be significant disagreement between the parties over whether Minnesota or Ohio law applies to this dispute. That question is irrelevant to our disposition of these issues. Federal law would preempt Plaintiffs' claims regardless of whether Minnesota or Ohio law applied.

or at least "in addition to" federal requirements. Plaintiffs' request to amend was futile.

Finally, Plaintiffs ask us to revisit our holding in *Kemp*. We may not do so. "A panel of this Court cannot overrule the decision of another panel. The prior decision remains controlling authority unless an inconsistent decision of the United States Supreme Court requires modification of the decision or this Court sitting en banc overrules the prior decision." *Salmi v. Secretary of Health and Human Services*, 774 F.2d 685, 689 (6th Cir.1985). Plaintiffs cite no authority that would allow us to revisit this court's earlier holding. We hold, therefore, that the district court did not err in denying Plaintiffs leave to amend, because the proposed amendments are futile as described by the district court, this court in *Kemp*, and the Supreme Court in *Buckman*.

CONCLUSION

For the foregoing reasons, we **AFFIRM** the decision of the district court.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethel Cupek, et al.	)	
Plaintiffs,	)	Case No. C-1-97-105
	)	
vs.	)	
	)	
Medtronic, Inc.,	)	
Defendant.	)	

ORDER

This matter is before the Court on Plaintiffs' Motion to Reinstate Litigation and Motion for Leave to File An Amended Complaint (Doc. No 32). For the reasons set forth below, Plaintiffs' Motion to reinstate the litigation is well-taken and is GRANTED; Plaintiffs' motion to file an amended complaint is GRANTED IN PART AND DENIED IN PART.

I. Procedural Background

Plaintiffs in this case were implanted with heart pacemaker devices which employed either 4004 or 4004M pace maker leads manufactured by Defendant Medtronic, Inc. ("Medtronic"). A pacemaker lead sends an electrical current to the heart in order to sense and correct irregular heartbeats. Medtronic is a Minnesota corporation with its principal place of business located in Minneapolis, Minnesota. Plaintiffs are all citizens of states other than Minnesota. The subject matter jurisdiction of this Court is founded upon diversity pursuant to 28 U.S.C. § 1332.

On January 24, 1997, Plaintiffs filed a complaint (Doc. No.1) against Medtronic under state last for strict products liability (Count I), negligence and negligent misrepresentation (Count II), negligence per se (Count III), failure to warn (Count IV), breach of implied warranties (Count V), breach of express warranties (Count VI), fraudulent misrepresentation (Count VII), intentional infliction of emotional distress (Count VIII), negligent infliction of emotional distress (Count IX), fear of future product failure (Count X), and loss of consortium (Count XI). The general theory espoused by Plaintiffs was that the pacemaker leads were defective in terms of their design, manufacture, and accompanying warnings, that Medtronic knew they were defective when it marketed them, that, essentially, Medtronic defrauded the Food and Drug Administration into approving the leads for use.

On May 27, 1999, the Court entered an order (Doc. No. 28) administratively closing this case without prejudice to reopen pending the resolution of an appeal taken by the plaintiff in Kemp v. Medtronic, Inc., C-1-97-103 (S.D. Ohio) (Beckwith, J.). The Kemp case presented claims against Medronic identical to the ones asserted here with regard to the 4004M pacemaker lead. Understanding the procedural history of the Kemp is case is critical to resolving the motions pending in this case. Therefore, the Court will devote substantial time and space explaining the issues and outcome of Kemp.

In Kemp, the Court ruled on two separate motions for summary judgement filed by Medtronic. In its first motion for summary judgment, Medtronic argued that Mrs. Kemp's state law claims were preempted by the Medical Device Amendments ("MDA"), 21 U.S. C. § 360k, to the Food, Drug, and Cosmetic Act. The MDA preempts any state law requirement which is different from or in addition to any requirement imposed by the Act. The main issues presented on

the first motion for summary judgment were whether the FDA's premarket approval ("PMA") and PMA supplement process, under which Medtronic obtained approval to market the 4004m lead, established any specific federal requirement under the Act with respect to the lead, and, if so, whether a state law judgment in Mrs. Kemp's favor on any of her claims would impose a state requirement different from or in addition to the federal requirement.

In answering the questions presented, the Court found that the PMA Supplement process established specific federal requirements relative to the 4004M lead. Therefore, Mrs. Kemp's claims would be preempted if judgment on her claims would impose requirements different from or in addition to the federal requirements. The Court then found that claims based on defective design, defective warning, and non-conformance to warranties were preempted because the claims would impose additional or different requirements than the federal requirements. With respect to the manufacturing defect claim, the Court held that a claim for negligence despite adherence to FDA standards was preempted, but that a claim for negligent adherence to the standards imposed by the PMA was not preempted. The Court noted, however, that Mrs. Kemp had not asserted a claim for negligent adherence to the PMA requirements. The Court did, however, grant leave for Mrs. Kemp to file amended complaint which alleged that her 4004M lead deviated from the specifications approved by the FDA in the PMA and PMA Supplement. Rounding out the order, the Court ruled that Mrs. Kemp's state law claim for fraud on the FDA was preempted by federal law. See generally Kemp v. Medtronic, C-1-97-103 (S.D. Ohio Jan. 12, 1999) (Doc. No. 159).

Following the Court's ruling on summary judgment, Mrs. Kemp filed an eight count amended complaint. At a

pretrial hearing, the Court granted Medtronic's motion for judgment on the pleadings on five counts and partially granted the motion on one other count on the grounds the claims asserted therein were essentially restatements of claims the Court had previously ruled were preempted by federal law. What remained after granting the motion for judgment on the pleadings were claims for negligence per se and strict liability based on Medtronic's alleged failure to build the 404M lead in conformity with FDA specifications and a derivative state law claim for loss of consortium.

The parties then filed a cross-motions for summary judgment on the remaining claims. Mrs. Kemp's theory of the case was that the PMA specifications required Medtronic to coat the 4004M lead with 500 angstroms of platinum sputtering in order to prevent metal induced oxidation ("MIO"), that Medtronic did not coat the lead with 500 angstroms of platinum sputtering, and that this omission caused her lead to fail. The Court ruled, however, that while the PMA required Medtronic to coat the lead with platinum sputtering, the PMA did not require a particular thickness of sputtering. Therefore, Plaintiff's claim was preempted because it would impose a requirement different from or in addition to the PMA requirements. Furthermore, it was undisputed in the case that the lead did in fact have a platinum sputter coating. As a consequence, the Court granted Medtronic's motion for summary judgment, and denied Mrs. Kemp's motion for summary judgment, as to the negligence per se and strict liability claims. The Court also granted Medtronic's motion for summary judgment on the loss of consortium claim on the grounds that it was derivative of the other claims. See id. Doc. No. 211.

Mrs. Kemp then filed an appeal of this Court's judgment to the Sixth Circuit Court of Appeals. On November

1, 2001, the Sixth Circuit issued an opinion affirming the judgment of this Court in all respects. See Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000) ("Kemp I"). The Court first found that the PMA and PMA Supplement process impose specific federal requirements applicable to the device. See id. at 227-28. The Court next found that although a claim that the lead did not conform to FDA specifications established through the specifications established through the PMA process was not necessarily preempted, it too rejected Mrs Kemp's argument that the PMA Supplement required 500 angstroms of platinum sputtering. Therefore, the Court found, the negligence per se claim was preempted by federal law. Id. at 230-32. The Court next found that state law claims for fraudulent misrepresentation and fraud on the FDA are preempted by federal law. Id. at 232-36.

The Court next ruled that state law claims for failure to warn based on the alleged inadequacy of warnings approved by the FDA are preempted by federal law. See id. at 236. In relation to this claim, Mrs. Kemp argued that Medtronic negligently failed to warn of defects it became aware of after receiving FDA approval. The Court ruled, however, that Mrs. Kemp presented that argument for the first time on appeal and that, therefore, it could not property address that claim. See id. at 237. Accordingly, the Court declined to decide whether federal law preempted a failure to warn claim based on information obtained subsequent to FDA approval of the device. Id. The Court then issued a second, unpublished, opinion on Mrs. Kemp's petition for rehearing which reiterated that state law claims based on alleged failure to comply with federal regulations and FDA conditions of approval are preempted by federal law. See Kemp v. Medtronic, Inc., No. 99-3720, 2001 WL 91119, at *1 (6th Cir. Jan. 26, 2001) ("Kemp II"). In addition, the Court rejected Mrs. Kemp's

contention that the Court improperly refused to consider her post-FDA approval failure to warn claim. See id. at *2.

Following the issuance of the opinion in Kemp I, Medtronic filed a motion to lift the stay in this case and simultaneously moved for summary judgment on Plaintiffs' claims based on the decision in Kemp I, and the arguments it presented to this Court in its briefs in that case. See Doc. No. 29. Plaintiffs initially opposed Medtronic's motion to lift the stay because the Kemp appeal was not finalized due to the pending petition for rehearing en banc and planned petition for writ of certiorari to the U.S. Supreme Court. Subsequently, however, the parties filed a stipulation continuing the stay pending final resolution of the Kemp appeals process. See Doc. No. 31. As noted above, the Sixth Circuit denied Mrs. Kemp's petition for rehearing en banc on January 26, 2001. On October 1, 2001, the Supreme Court denied Mrs. Kemp's petition for a writ of certiorari. See Kemp v. Medtronic, Inc., 122 S. Ct. 48 (2001).

On October 4, 2001, Plaintiffs in this case filed the present motions to reinstate this case to the active docket and for leave to file an amended complaint. Plaintiffs attached a copy of the proposed amended complaint to their motion. Medtronic does not oppose the motion to reinstate the case, but only for purposes of ruling on its pending motion for summary judgment. Medtronic opposes Plaintiffs' motion to amend the complaint principally on the grounds that granting leave to amend would be futile.

II. The Proposed Amended Complaint

Plaintiffs seek leave to file an amended complaint in order to, inter alia, "clarify certain post-manufacture failure to warn/failure to recall claims based on information obtained by

Medtronic post-FDA approval." See Doc. No. 32, at 1. In addition, Plaintiffs contend "that the Sixth Circuit wrongly decided the Kemp appeal." Id. Therefore, Plaintiffs assert claims rejected in the Kemp decision in order to preserve those claims to argue on appeal for a modification or reversal of existing law or the establishment of new law. See id. at 1-2. The proposed amended complaint contains eight counts consisting of four "new" claims and four "old" claims.

Count I of the proposed amended complaint asserts a claim for failure to warn based on information learned after FDA review and approval of the 4004 and 4004M leads. Specifically, this count alleges that Medtronic had a continuous duty to warn after its pacemaker lead was sold to a customer which is independent of any applicable federal regulations. Count I alleges that the duty required Medtronic to issue new or additional warnings based on new or additional information that would have caused a reasonable manufacturer to amend existing warnings. Count I further alleges that following FDA approval of the 4004 and 4004M leads, Medtronic obtained information which indicated that MIO would cause the leads to fail prematurely but that Medtronic continued to manufacture, market, and sell the leads without issuing additional warnings.

Count II of the proposed amended complaint states a claim for negligent failure to recall and/or withdraw the 4004 and 4004M leads from the market based on information obtained after FDA review and approval of the leads. This count alleges that a manufacture has an ongoing and continuous duty to recall a product from the market and/or cease manufacturing and selling the product when it learns that the product is dangerous and can cause injury when used in a foreseeable or intended manner. Count II alleges that this duty is independent of any other federal regulations. Count II further alleges that Medtronic breached this duty by not

recalling the 4004 and 4004M leads after obtaining information indicating that the leads would fail and not perform as intended.

Count III of the proposed amended complaint asserts a claim for negligence per se based on failure to comply with federal requirements consistent with state requirements. Count III alleges that Medtronic failed to comply with unspecified applicable CFR regulations in it 4004/4004M PMA Supplement applications. Count III further alleges that by approving the 4004/4004M, the FDA established additional requirements for the design and manufacture of the leads and that Medtronic failed to manufacture the leads as required by the FDA.

Count IV of the proposed amended complaint alleges that in submitting the PMA Supplement applications for the 4004 and 4004M leads, Medtronic was obligated to comply with the FDA conditions of approval set forth in 21 C.F.R. § 814.84. Count IV then states a number of ways in which Medtronic allegedly violated the FDA's conditions of approval. Count IV alleges that Medtronic's alleged failure to comply with 21 C.F.R. § 814.84 invalidated the FDA's approval of the leads. The apparent theory of this claim is that it the FDA's approval of the leads was invalid, then there are no specific federal requirements applicable to the leads, and hence, no preemption of state law claims.

Finally, as noted above, Counts V through VIII of the proposed amended complaint assert claims which Plaintiffs admit are precluded by the current law of this Circuit. Plaintiffs argue, however, that the applicable law was wrongly decided and state that they intend to ask for a reversal or modification of existing law on appeal.

III. Motion to Amend Standard

Rule 15 (a) of the Federal Rules of Civil Procedure provides:

> A party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served or, if the pleading is one to which no responsive pleading is permitted and the action has not been placed upon the trial calendar, the party may so amend it at any time within 20 days after it is served. Otherwise a party may amend the party's pleading only by leave of court or by written consent of the adverse party; and leave shall be freely given when justice so requires.

Fed. R. Civ. P. 15 (a). As the Rule points out, leave to amend shall be freely granted. The thrust of the provision "is to reinforce the principle that cases should be tried on their merits rather than on the technicalities of pleadings." Tefft v. Seward, 689 F.2d 637, 639 (6th Cir. 1982). Delay that is not intended to harass the defendant is not in itself a permissible reason to refuse leave to amend. Id. at 639 n.2. Furthermore, there must be " at least some significant showing of prejudice to the opponent" if the motion is to be denied. Moore v. City of Paducah, 790 F.2d 557, 562 (6th Cir. 1986). The case law of this Circuit manifests " liberality in allowing amendments to a complaint." Id. Absent undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, or if allowing the amendment would be futile, a court should grant leave to amend. Thiokol Corp. v. Department of Treasury, 987 F.2d 376, 383 (6th Cir. 1993) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)). For purposes of Rule 15(a), an amendment

is futile if it would not withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. See Rose v. Hartford Underwriters Ins. Co., 203 F.3d 417, 420 (6th Cir. 2000).

IV. Analysis

In its brief opposing the motion for leave to amend, Medtronic does not argue that undue delay, bad faith, or dilatory motive accompanies Plaintiffs' motion. Similarly, Medtronic does not argue that it will suffer undue prejudice if Plaintiffs are permitted to amend their complaint. Therefore, whether the Court should grant leave to amend will depend upon whether the claims asserted in the proposed amended complaint are futile.

Medtronic suggests, however, that it would not be an abuse of discretion for the Court to address its pending motion for summary judgment before considering whether Plaintiffs should be allowed to amend their complaint. Despite this argument, Sixth Circuit precedent suggests otherwise. In Marks v. Shell Oil Co., 830 F 2d 68 (6th Cir.1987), the Court held that the district court abused its discretion by granting a motion for summary judgment based on the original complaint. See id. at 70. Therefore, the Court will address Plaintiffs' motion for leave to amend before issuing any ruling on the pending motion for summary judgment.[3]

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[3]This action is of course appropriate despite Medtronic's contention that Plaintiffs have already pled some of their proposed claims, albeit perhaps unclearly, in the original complaint. In Marks, the Court noted that the proposed amended complaint "expanded considerable upon the original complaint's claims of wrongful nonrenewal of the franchise

The Court starts the analysis by setting forth the Rule 12(b)(6) standard of review. A motion to dismiss pursuant to Rule 12(b)(6) operates to test the sufficiency of the complaint. In its consideration of a motion to dismiss under Rule 12(b)(6), the court is required to construe the complaint in the light most favorable to the Plaintiff and accept all well-pleaded factual allegations in the complaint as true. Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) and Roth Steel Products v. Rhodes Corp., 705 F.2d 134, 155 (6th Cir. 1983). A court, however, will not accept conclusions of law or unwarranted inferences which are presented as factual allegations. Blackburn v. Fisk University, 443 F.2d 121, 124 (6th Cir. 1974). A court will, though, accept all reasonable inferences that might be drawn from the complaint. Fitzke v. Shappell, 468 F.2d 1072, 1076-77 n.6 (6th Cir. 1972).

The Court addresses the proposed amendment somewhat in reverse fashion in order to dispose first of those claims which clearly are futile. As noted Plaintiffs essentially admit that Counts V through VIII are precluded by existing case law. Plaintiffs, however, believe that the controlling case law was wrongly decided and, therefore, intend to argue for a change of law before the Court of Appeals. This Court, of course, is in no position to tell the Sixth Circuit that its opinion in Kemp was wrong even if it were inclined to do so, which it is not. It is clear, however, that because current case law

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under the [Petroleum Marketing Practices Act]," see id. at 69, but nonetheless held that the district court should have considered the motion to amend before granting summary judgment. Therefore, according to Marks, even if Plaintiffs' proposed amended complaint only clarifies imperfectly pled claims, this Court should still consider the motion to amend before ruling on a motion for summary judgment.

precludes the claims asserted in Counts V through VIII, these counts fail to state claims for relief. Therefore, amending the complaint to include these claims would be futile. Accordingly, the Court would not permit Plaintiffs to file an amended complaint reasserting these claims.

Court IV of the proposed amended complaint also clearly asserts a futile claim. As indicated above, Count IV basically alleges that Medtronic was negligent per se in failing to comply with the FDA's conditions of approval set forth in the Code of Federal Regulations. Even read in the light most favorable to Plaintiffs, this count contains nothing more than a disguised fraud on the FDA claim. As Medtronic correctly points out, not only did the Sixth Circuit reject such a claim in Kemp, the U.S. Supreme Court recently held that a state law claim for fraud on the FDA is preempted by federal law. See Buckman Co. v. Plaintiffs' Legal Comm., 121 S. Ct. 1012, 1017 (2001). As the Supreme Court observed in Buckman, the FDA is amply armed to punish and deter those who do not comply with the applicable regulations. See id. Count IV would interject this Court into the FDA's decision-making processes with the undesirable effect of disrupting the comprehensive scheme which has been established for evaluating and approving medical devices. Accordingly, Count IV is clearly preempted and, therefore, fails to state a claim for relief. Consequently, the Court would not permit Plaintiffs to file an amended complaint containing proposed Count IV.

Whether Counts I through III are futile depends on whether the claims contained therein are preempted by the Medical Device Amendments. A noted above, a state law claim will be preempted by the MDA if would impose a requirement different from or in addition to the federal requirements. See 21 U.S.C. § 360k(a). Counts I and II seek to impose tort liability on Medtronic for its alleged negligent

failure to issue additional warnings and/or recall the 4004 and 4004M leads after the devices had been approved by the FDA upon obtaining information which indicated that the leads posed a health or safety risk. The Court finds that the liability Plaintiffs seek to impose in Counts I and II would constitute a state law requirement different from or in addition to the requirements imposed by the federal law. Therefore, the claims asserted in Counts I and II are preempted.

The Court first observes that the Food, Drug, and Cosmetic Act gives to the Secretary of Health and Human Services authority to issue a notification if a medical device presents a substantial risk of harm to public health. See 21 U.S.C. § 360h(a). This same section, however, gives the Secretary the discretion to withhold notice to individuals if he or she determines that giving notice would present a greater danger to the health of such individuals than no notice at all. See id. § 360h(a)(2). The Secretary is also authorized order [sic] manufacturers to cease distribution of a device upon finding there is a reasonable probability that a medical device intended for human use would cause serious, adverse health consequences or death. See id. § 360h(e)(1). This section further authorizes the Secretary to issue a recall order after providing an opportunity for the manufacturer to be heard. See id. § 360(e)(2).

The FDA has notification and recall authority which substantially parallels that authority given to the Secretary. See generally 21 C.F.R. Pt. 810 (Medical Device Recall Authority). In addition to its recall authority, the FDA has promulgated regulations requiring manufacturers to submit reports of corrections or removals of devices. See 21 C.F.R. § 806.10. Manufacturers are also required to submit to the FDA reports of individual adverse events. 21 C.F.R. § 803.50. Specifically, this section provides:

> Device manufacturers are required to report within 30 days whenever the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:
> (1) May have caused or contributed to a death or serious injury; or
> (2) Has malfunctioned and such device or similar device marketed by the manufacture would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F. R. § 803.50 This section states that information is reasonably known to a manufacture if it "can be obtained by analysis, testing or other evaluation of the device." See id. § 803.50(b)(1)(iii). Finally, the regulations provide that the FDA may decide to withhold notice of a mandatory recall if it "determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential." See 21 C.F.R. § 810.18.

What is apparent from reading the applicable statutes and regulations is that Congress and the FDA have established a complex and comprehensive infrastructure for monitoring and ensuring the continued safety and efficacy of approved medical devices. Significantly, despite this comprehensive minoring and reporting scheme, nothing in either the governing statute or the FDA regulations mandates that a manufacturer remove a device from the market or issue additional warnings if it learns or becomes reasonably aware that its medical device may cause or contribute to death or serious injury. This omission appears to be no accident. The Senate Report accompanying

The Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (1990), the legislative enactment which strengthened the Secretary's recall authority, acknowledges that the FDA's reliance on voluntary recalls by manufacturers did not provided the necessary consumer protection where potentially life-threatening devices remained on the market. See S. Rep No. 101-513, §§ I, II(B), III(11) (1990). Despite the awareness of this flaw in the system, however, Congress did not imposed [sic] upon manufacturers a duty to recall defective medical devices. Therefore, where Congress has acknowledge that the voluntary recall system was not completely effective, and has amended the system by imposing reporting requirements, but not recall and notification requirements, the Court must conclude that Congress did not intend for recalls and warnings to be issued in every case where a medical device may have contributed to death or injury. See, e.g., Northwest Airlines, Inc. v. Transport Workers Union of Am., AFL-CIO, 451 U.S. 77, 97 (1981) ("The presumption that a remedy was deliberately omitted from a statute is strongest when Congress has enacted a comprehensive legislative scheme including an integrated system of procedures for enforcement."). Indeed, both the statute and the regulations recognize that in some instances knowing that the device is potentially defective poses a greater risk to health than the defective device itself. In fact, upon receiving the incident reports that manufactures are required to submit, the FDA may well still conclude that the benefits of the device continue to outweigh its risks.

In light of this discussion, it is apparent that there is no federal requirements that a manufacturer recall a product or issue additional or amended warnings upon learning that a medical device potentially poses a health or safety risk. Thus, the claims in Counts I and II, which seek to impose liability for negligent failure to recall and negligent failure to warn based on information obtained post-FDA approval, would impose a

state requirement that is different from or in addition to the federal requirement.[4] Therefore, these claims are preempted by the MDA. Because the claims are preempted, Counts I and II fail to state claims for relief. Accordingly, the Court would not grant Plaintiffs leave to amend the complaint to assert the claims contained in Counts I and II.

Thus remaining for consideration is Count III, which states a claim for negligence per se for failure to comply with federal requirements consistent with state requirements. At first blush, this count appears to state nothing more than another variation of a fraud on the FDA claim. See Proposed Amended Complaint ¶ 54 ("Medtronic failed to comply with applicable CFR regulations in its Model 4004/400M PMA Supplement applications."). However, this count goes on to allege that the FDA's approval of the PMA Supplements established requirements for the design and manufacture of the leads and that Medtronic failed to manufacture the leads in accordance with the FDA requirements. Read in the light most favorable to Plaintiffs, this count fairly states a claim that Medtronic failed to build the leads in conformity with the approved PMA and PMA Supplements. This type of claim is not preempted by the MDA. See Kemp, 231 F.3d at 232. Therefore, with exception of striking ¶ 54, the Court would

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[4]The Court recognizes that Plaintiffs contend that Minnesota law imposes on manufacturers a continuing duty to warn of defects in products. The Court assumes without deciding that this duty includes a duty to recall defective products in certain circumstances. However, whether the law of a particular state recognizes the asserted cause of action is irrelevant to the analysis given that the liability Plaintiffs seek to impose would be a requirement different from or in addition to the federal requirement.

permit Plaintiffs to amend the complaint to state the claim alleged in Count III. Accordingly, to that extent, Plaintiffs' motion for leave to amend the Complaint is well-taken and is GRANTED.

The Court's rulings on the viability of the various claims has rendered much of the proposed amended complaint superfluous. Therefore, in order to simplify and clarify further proceedings, Plaintiffs shall within ten days of the date of this order file an amended complaint which conforms to the rulings of this order and contains only the factual allegations necessary to support the claim asserted in Count III of the proposed amended complaint.

Conclusion

In conclusion, the Court finds that Plaintiffs' motion to reopen the case is well-taken and is GRANTED. Plaintiffs' motion for leave to amend the complaint is GRANTED IN PART AND DENIED IN PART. Counts I, II, , IV, and V through VIII are preempted by federal law. Therefore, the motion for leave to amend the complaint to assert the claims in those counts is not well-taken and is DENIED. However, with the exception of ¶ 54, Count III of the proposed amended complaint is not preempted by federal law. Therefore, to that extent, the motion for leave to amend the complaint is well-taken and is GRANTED.

IT IS SO ORDERED

Date 12-10-01 /s/

Sandra S. Beckwith
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethel Cupek, et al.	)	
Plaintiffs,	)	Case No. C-1-97-105
	)	
vs.	)	
	)	
Medtronic, Inc.,	)	
Defendant.	)	

ORDER

This matter is before the Court on Plaintiffs' motion for reconsideration (Doc. No. 41). For the reasons set forth below, Plaintiffs' motion is not well-taken and is DENIED.

The Court described fully the procedural background of this case in its order of December 11, 2001 (Doc. No. 37). Suffice to say for present purposes that this case began with Plaintiffs suing Defendant Medtronic, Inc. under a number of state law tort and products liability theories because they were implanted with allegedly defective pacemaker leads manufactured by Medtronic. The case was then stayed while a case presenting identical legal issues, Kemp v. Medtronic,Inc., C-1-97-103, wound its way to a conclusion. Ultimately, in the Kemp case, this Court determined that except for claims that Medtronic failed to build a pacemaker lead in conformity with the applicable PMA and/or PMA Supplement, all state law tort claims and products liability claims were preempted by the Medical Device Amendments to the Food & Drug Act. 20 U.S.C. § 360(k)(a) [sic]. The Sixth Circuit Court of Appeals affirmed that decision. See Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000).

Following the Sixth Circuit's decision in Kemp, Medtronic moved to reopen this case for the purpose of filling a motion for summary judgment on Plaintiffs' claims. Plaintiff initially opposed reopening this case because a petition for a writ of certiorari was still pending before the U.S. Supreme Court in Kemp. Ultimately, however, the Supreme Court denied the petition and Plaintiffs conceded that it was time to reopen this case.

Upon reopening this case, however, Plaintiffs moved to file an amended complaint. See Doc. No. 32. Plaintiffs' proposed amended complaint would have retained each claim that was no longer legally viable in the wake of the Court's decision in Kemp and would have added new claims based on a theory that, after having learned that the 4004 and 4004M leads were dangerous, Medtronic was negligent in failing to recall these leads from the market and was negligent in failing to issue additional warnings on these leads. Medtronic opposed the motion for leave to amend on the grounds that Plaintiffs were either trying to redress claims that had already been rejected by the Sixth Circuit in Kemp and/or that their claims were futile because of MDA preemption.

On December 11, 2001, the Court issued an order granting in part and denying in part Plaintiffs' motion for leave to amend the complaint. Doc. No. 37. The court initially noted that Plaintiffs admitted that some to their claims were precluded by the Kemp decision, and therefore, would not permit Plaintiffs to re-allege those claims on the grounds of futility. The Court also found that Plaintiffs were attempting to reconfigure a fraud on the FDA claim—one of the claims rejected in Kemp and a claim which the U.S. Supreme Court subsequently held is preempted by the MDA—and, therefore, refused to allow Plaintiffs to amend their complaint to allege that claim. The Court also found that Plaintiff's claims related

to post-market failure to warn and failure to withdraw the leads from the market were preempted by the MDA. The Court, therefore, found that these claims were futile and declined to permit Plaintiffs to assert these claims in an amended complaint. The court did find, however, that the proposed amended complaint contained allegations that Medtronic failed to build the 4004 and 4004M leads in conformity with the requirements of the PMA and PMA Supplement. Therefore, the Court held that this claim was not futile and invited Plaintiffs to file an amend complaint containing only the factual allegations necessary to support such a claim.

Plaintiffs did not, however, file the amended complaint suggested by the Court. Instead, Plaintiffs filed the present motion for the Court to reconsider its order denying them leave to amend the complaint. Although the Court admits that it does not completely follow Plaintiffs' reasoning, they appear to argue that by addressing the perception issue at the amendment stage, the Court has both denied them of a full opportunity to brief the preemptive effect of MDA on the proposed claims and deprived them of the chance to save the preemption issue for appeal. The Court disagrees.

As the Court stated in the earlier order, when the opposing party argues that granting leave to amend would be futile, the district court's standard of review in assessing futility becomes the Rule 12(b)(6) standard of review. Rose v. Hartford Underwriters Ins. Co., 203 F.3d 417, 420 (6th Cir. 2000). In turn, the Rule 12(b)(6) standard assesses the legal sufficiency of the plaintiff's claims. See Miller v. Currie, 50 F.3d 373, 377 (6th Cir. 1995) (explaining that a court " should deny [a Rule 12(b)(6)] motion unless it is clear that the plaintiff can prove no set of facts in support of her claim that would entitle her to relief"); Mayer v. Mylod, 988 F.2d 635, 638 (6th Cir. 1993) ("The purpose of Rule 12(b)(6) is to allow a

defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even it everything alleged in the complaint is true."); Scheid v. Fanny Farmer Candy Shops, Inc., 859 F.2d 434, 436 (6th Cir. 1988) ('A Rule 12(b)(6) motion tests whether a cognizable claim has been pleaded in the complaint."). Therefore, in assessing whether to grant Plaintiffs leave to amend their complaint, the Court necessarily and correctly analyzed the preemptive effect of the MDA on Plaintiffs' proposed claims because preempted claims are not legally cognizable. It would turn the futility aspect of Rule 15(a) on its head to allow Plaintiffs to amend their complaint and then determine whether their claims are preempted.

Moreover, Plaintiffs had a fair opportunity to brief the preemptive effect of the MDA on their claims because Medtronic raised the issue in its memorandum in opposition to the motion for leave to amend and again in its notice of supplemental authority. See Doc. Nos. 34 & 36. Plaintiffs could have addressed preemption in their reply brief but instead focused on whether Minnesota law recognizes claim for post-market failure to warn. As the Court stated in the earlier order, whether Minnesota law permits such a claim is irrelevant if the liability Plaintiffs would impose is a requirement different than or in addition to the requirements of federal law. See Doc. No 37, at 18 n.2. The fact that Plaintiffs perhaps focused their attention in the wrong direction does not mean that they have been deprived of an opportunity to brief the merits of the preemption issue. Plaintiffs did not respond at all to Medtronic's notice of supplemental authority and so waived any further briefing opportunity there. In short, Plaintiffs had sufficient notice and opportunity to address preemption before the Court ruled on their motion for leave to amend.

Finally, the Court believes that the preemption issue has been preserved for appellate review. As stated, the futility

analysis incorporates the Rule 12(b)(6) standard. In denying Plaintiffs leave to amend their complaint on futility grounds, the Court has in effect dismissed those claims for failure to state claims upon which relief can be granted. The Court of Appeals will review that decision under the de novo standard of review rather than for abuse of discretion. See Blakely v. United States, 276 F.3d 853, 874 (6th Cir. 2002) ("[W]hen the district court's decision is based on the futility of the amendment, i.e., that the amended complaint would not withstand a motion to dismiss, we review the district court's decision de novo."). The Court of Appeals will not be able to make its decision without reviewing MDA preemption. Therefore, in the Court's opinion, Plaintiffs have not lost their right to appeal the Court's rulings on MDA preemption.

Accordingly, for the reasons state [sic], Plaintiff's motion for reconsideration is not well-taken and is DENIED.

IT IS SO ORDERED

Date 11-19-02 /s/
Sandra S. Beckwith
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Ethel Cupek, et al.	)	
Plaintiffs,	)	Case No. C-1-97-105
	)	
vs.	)	
	)	
Medtronic, Inc.,	)	
Defendant.	)	

ORDER

This matter is before the Court on Defendant Medtronic, Inc.'s motion for summary judgment (Doc. No. 29) and Plaintiffs' response to the Court's show cause order of September 14, 2003 (Doc. No. 65). For the reasons set forth below, Medtronic's motion for summary judgment is well-taken and is GRANTED.

The factual and procedural background of this case is well-documented in several other orders issued by the Court. See Doc. Nos. 37, 54, 62. The Court, therefore, need not again recount the case history. On September 14, 2003, the Court ordered Plainfiffs to show cause why Medtronic's motion for summary judgment should not be granted on their remaining state law claims for negligence per se in the manufacture of the 4004 and pacemaker leads.

In response, Plaintiffs state that in opposition to Medtronic's motion, they would present evidence that Medtronic deviated from the requirements of the PMA Supplement and the FDA conditions of approval by implementing changes to the thickness of the platinum

sputtering of pacemaker leads without submitting reports detailing the engineering changes to the FDA. See Doc. No. 65, at 6-10. Assuming, however, that Plaintiffs are in possession of such evidence and that it indeed shows that Medtronic changed the platinum sputtering thickness without submitting the required reports to the FDA, this evidence fails to establish that Medtronic was negligent per se in manufacturing Plaintiffs' pacemaker leads. This contention is only a slight tweaking of Plaintiffs' theory that the PMA supplements for the 4004 and 4004M leads required Medronic to manufacture the leads with a specific thickness of platinum sputtering. However, as this Court found in Kemp v. Medtronic, Inc., C-1-97-103 (S.D. Ohio 1999) (Doc. No. 210), and as affirmed by the Sixth Circuit Court of Appeals, Kemp v. Medronic, Inc., 231 F.3d 216, 232 (6th Cir. 2000), the FDA's approval of the leads only required Medtronic to make the leads with a platinum sputtering coating; it did not require Medtronic to apply a specific thickness of sputtering. Thus, even if Medtronic did vary the thickness of the platinum sputtering without filing the proper reports with the FDA, so long as the pacemakers leads had some platinum sputtering, and Plaintiffs do not contend that they did not, Medtronic was not negligent per se manufacturing the leads. To the extent that Plaintiffs contend that Medtronic was negligent per se in failing to file the proper reports with the FDA, that claim is preempted by federal law. Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Therefore, summary judgment in Medtronic's favor on this theory of liability is appropriate.

Accordingly, for the reasons stated, Medtronic, Inc.'s motion for summary judgment is well-taken and is GRANTED. This case is closed.

IT IS SO ORDERED

Date January 13, 2004 /s/
Sandra S. Beckwith
United States District Judge

Supreme Court, U.S.
FILED
SEP 15 2005
OFFICE OF THE CLERK

NO. 05-22

IN THE
Supreme Court of the United States

M. R. KNISLEY, *et al.*,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONERS

LOUIS F. GILLIGAN
GREGORY M. UTTER
JOSEPH M. CALLOW, JR.
JASON M. COHEN
KEATING, MUETHING & KLEKAMP, P.L.L.
One East Fourth Street
Cincinnati, Ohio 45202
(513) 579-6400

ALLISON M. ZIEVE
Counsel of Record
BRIAN WOLFMAN
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street, NW
Washington, DC 20009
(202) 588-1000

Counsel for Petitioners
M. R. Knisley, *et al.*

September 2005

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REPLY BRIEF FOR PETITIONERS

Respondent Medtronic, Inc. concedes the conflict among the lower federal and state courts on the question presented. It offers two arguments why the petition should nonetheless be denied. First, Medtronic contends that the courts on the no-preemption side of the conflict are going to reverse themselves. However, Medtronic made the same prediction in opposition to two petitions for certiorari filed four years ago, and time has proven the prediction to be wrong. Second, Medtronic argues that decisions finding no preemption are incorrect. Petitioners of course believe those decisions to be correct. Yet whichever group of cases has properly construed 21 U.S.C. § 360k(a) and *Medtronic v. Lohr*, 518 U.S. 470 (1996), the continuing conflict will not be resolved without the Court's intervention.

1. Medtronic does not deny that the lower courts are in conflict over the question presented in this case: whether the preemption provision of the Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval ("PMA"). Indeed, Medtronic does not dispute the existence of a conflict on either side of the preemption analysis: Medtronic (at 17) agrees that a conflict exists over whether premarket approval establishes a preemptive requirement on the federal side of the analysis. *Compare Goodlin v. Medtronic*, 167 F.3d 1367, 1373-77 (11th Cir. 1999) (PMA not a device-specific requirement for purposes of preemption under § 360k(a)), *and Weiland v. Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999) (same), *with Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) (PMA preempts damages claims), *and Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) (same). And Medtronic acknowledges (at 19) that the courts disagree over whether state-law damages claims, such as those at issue here, are too general to trigger

preemption under the Court's analysis in *Lohr* and the FDA's long-standing preemption regulation, 21 C.F.R. § 808.1. *Compare Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (failure-to-warn claim predicated upon general duties applicable to every manufacturer not preempted), *and Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) (same), *with Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (state-law damages claims preempted by § 360k(a)), *and Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997) (same).

2. Unable to deny the conflict among the lower courts, Medtronic argues that the conflict may "diminish" in light of two implied preemption cases—*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000)—and an amicus brief in *Horn*, in which the United States reversed its position on the preemptive effect of PMA. Medtronic's speculation is unfounded.

First, Medtronic's focus on *Buckman* is a distraction, for that case does not address the question presented here. In fact, Medtronic made the same argument—that courts would revisit and reverse their no-preemption rulings in light of *Buckman*—in opposing the petitions for certiorari in *Kemp v. Medtronic*, No. 00-1766, and in *Martin v. Medtronic*, No. 01-441. Yet although four years have passed since *Buckman* was decided, the split in authority is as deep as ever.

That *Buckman* has not affected cases construing section 360k(a) is not surprising. In holding that a fraud-on-the-FDA claim is impliedly preempted, *Buckman* explicitly distinguished claims that "rely[] on traditional state tort law which had predated the federal [MDA] enactments in question." 531 U.S. at 353. Moreover, Buckman involved neither a PMA device

nor preemption under section 360k(a). *Buckman*'s only discussion of PMA appears in a description of the medical device regulatory scheme. *Id.* at 344. That description is taken wholly from FDA regulations and from *Lohr*, and thus has always been available to the courts on both sides of the post-*Lohr* conflict on which the petition is based. Aside from that background discussion, *Buckman* mentions PMA only in passing. *Id.* at 348, 349.

Likewise, Medtronic twice suggests (at 1, 15) without explanation that the Court's 2000 decision in *Geier* will affect the long-standing conflict on the question presented. *Geier* involved preemption under the National Highway Traffic Safety Act. The Court found no express preemption but held that the plaintiff's damages claims were impliedly preempted because they would frustrate the agency's objective with regard to a specific motor vehicle safety standard. *Geier* has had no effect on the development of case law involving preemption under section 360k(a), and Medtronic does not cite any case suggesting otherwise.

Last, Medtronic points to an amicus brief filed by the United States in *Horn*, 376 F.3d 163, a Third Circuit case in which the government argued that PMA preempts damages claims. That brief also will not spur the lower courts to alter their prior holdings. Generally, statements contained in amicus briefs do not have the requisite formality to warrant deference or other significant weight. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000). This principle is particularly important here, where the government twice filed amicus briefs in this Court arguing against preemption, but then disavowed its own arguments and filed an amicus brief in *Horn* taking the opposite position. *Compare* Br. of U.S. as Amicus Curiae in *Smith Industries*

Medical Systems v. Kernats, S. Ct. No. 96-1407, at 14-18 (filed Dec. 1997), *and* Br. of U.S. as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 15, 1996), *with* Br. of U.S. as Amicus Curiae in *Horn v. Thoratec, Corp.*, 3d Cir. No. 02-4597, 2004 WL 1443720 (filed May 14, 2004). Thus, in *Bates v. Dow Agrosciences*, where the United States filed an amicus brief arguing a position directly opposite to the position it took in an earlier brief, the Court gave the later brief little attention and no weight. *See generally* 125 S. Ct. 1788 (2005); *see also id.* at 1801 (rejecting argument that provision unambiguously preempts tort claims as "particularly dubious" given that the United States earlier advocated the contrary position).

Not only does the government's position in the *Horn* amicus brief contradict the arguments it made twice before this Court, it contradicts the FDA's previous construction of its own regulation, 21 C.F.R. § 808.1(d), to which *Lohr* gave substantial weight. *See* 518 U.S. at 496-97, 498-99; *id.* at 505-06 (Breyer, J., concurring). Thus, the amicus brief deserves no deference from the courts. *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see Mead Corp.*, 533 U.S. at 228 (degree of deference due to government depends on, among other things, consistency and formality of government's position); *cf. Maislin Indus. v. Primary Steel, Inc.*, 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning."). In these circumstances, far from diminishing the confusion, the *Horn* amicus brief adds to it.

Last Term in *Bates*, the Court rejected a pesticide manufacturer's sweeping preemption argument and the holdings

of a majority of the circuit courts, based on a preemption provision "similarly worded" to section 360k(a). 125 S. Ct. at 1800. *Bates* represents the latest in a series of cases in which the Court has disagreed with a majority of lower courts as to the effect of an express preemption provision on state-law damages claims. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 63-64 (2002); *Geier*, 529 U.S. at 867-68; *Lohr*, 518 U.S. at 492-502; *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). The lower courts' responses to the Court's recent preemption jurisprudence demonstrates, not that time will resolve the conflicts, but that the Court's guidance with respect to the specific question presented here is urgently needed.

3. Attempting to minimize the disarray in the lower courts, Medtronic focuses on a few of the cases cited in the petition and argues that the cases were wrongly decided and "unlikely to survive." Opp. 17. However, Medtronic does not cite a single case from any of the relevant federal circuits or state courts, or from the trial courts within those jurisdictions, that suggests that these appellate decisions will be revisited.

Medtronic's descriptions of the opinions it selects for discussion consistently mischaracterize the courts' analyses. First, Medtronic misrepresents the reasoning of *Goodlin v. Medtronic*, 167 F.3d 1367, omitting key aspects of the opinion and selectively quoting from two pages of a 10-page analysis. Opp. 17. Just as Medtronic does here, in *Goodlin*, Medtronic relied on the rigor of the PMA review. The Eleventh Circuit correctly understood, however, that the PMA process does not result in any regulation or substantive statement, but only in a finding that the company has demonstrated reasonable assurance of a device's safety and effectiveness. 167 F.3d at 1375. The court explained that "while a PMA review is considerably more rigorous and detailed than the premarket

review notification [510(k)] process at issue in [*Lohr v.*] *Medtronic*, it is, in fact, no more 'specific a requirement.'" *Id.* at 1376 (quoting *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997)).

Next, Medtronic sets its sights on *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, which also holds that PMA does not preempt damages claims. Citing 21 C.F.R. § 814.80, the generally applicable regulation prohibiting manufacturers from altering the manufacturing or labeling of a PMA device in ways inconsistent with the conditions of approval, Medtronic disputes *Weiland*'s statement that PMA imposes no substantive requirements on the design or manufacture of the device. Opp. 18. To begin with, the relevant FDA regulations regarding 510(k) devices are very similar to the PMA regulation cited as an example by Medtronic. *See* 21 C.F.R. § 807.81(a)(3) (prohibiting significant design or manufacturing changes prior to new 510(k) submission); *see also* 21 C.F.R. § 820.1 (good manufacturing practices regulations applicable to both PMA and 510(k) devices); *id.* § 801.109 (prescription device labeling regulations applicable to both PMA and 510(k) devices). Nonetheless, the Court in *Lohr* held that section 510(k) regulation did not trigger section 360k(a).

Furthermore, in the portion of *Weiland* cited by Medtronic, the court is simply explaining that the design of the device originated with the company, and that the FDA had the authority to impose specific design standards but had not done so. 721 N.E.2d at 1152-53. Although it is true that PMA imposes various requirements on a manufacturer, both *Lohr*, 518 U.S. at 500, and the relevant FDA regulation, 21 C.F.R. § 808.1, instruct courts to consider whether those requirements are device-specific and whether state-law damages claims are

counterparts to specific requirements. Notably, Medtronic never undertakes that analysis. That is, Medtronic never identifies just what requirement a state-law damages claim would impose on the company, much less how that requirement would be different from or in addition to a particular federal requirement imposed through the PMA process. *See also Bates*, 125 S. Ct. at 1799 ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.").

Turning to cases that hold that state-law damages claims are too general to fall within the preemptive scope of section 360k(a), Medtronic ignores many of the state-court decisions cited in the petition and focuses almost exclusively on *Oja v. Howmedica*, 111 F.3d 782. While conceding that *Oja* conflicts with the decision below, Medtronic faults *Oja* for "never directly consider[ing] whether a finding of liability under a state common law duty would 'have the effect of establishing a substantive requirement for a specific device.'" Opp. 20 (quoting *Oja*, 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500)). In fact, the Tenth Circuit did "directly consider" that possibility and expressly found that "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device.'" *Oja*, 111 F.3d at 789. Medtronic also criticizes *Oja* for purportedly failing to recognize that, in *Lohr*, five members of this Court would have held that state-law damages claims can, in some circumstances, impose requirements preempted by section 360k(a). But *Oja* is fully consistent with that approach. The opinion applies *Lohr* at every step, *see generally id.* at 788-89, and holds that the common-law claims at issue were based on generally applicable duties that did not relate specifically to devices.

In addition to *Oja* and other cases, the petition cites *Niehoff v. Surgidev*, 950 S.W.2d at 822, as a case holding that, under *Lohr*, state laws of general applicability that apply to all products fall outside the preemptive scope of section 360k(a). Medtronic (at 19 n.11) responds that *Niehoff* involved an investigational device, not a PMA device. That statement is correct, as the petition itself states, *see* Pet. 17 n.6, but irrelevant. *Niehoff*'s holding that generally applicable state-law claims are not preempted concerns the state-law side of the section 360k(a) preemption analysis and, therefore, applies with equal force to claims involving PMA devices. Medtronic's claim that *Niehoff* did not so hold is belied by the decision itself, *see* 950 S.W.2d at 822, and by a subsequent decision of the Kentucky Court of Appeals, which reads *Niehoff* precisely as Petitioners do. *See Leslie v. Cincinnati Sub-Zero Prods., Inc.*, 961 S.W.2d 799, 802-03 (Ky. App. 1998).

Similarly, *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004), addressed preemption under section 360k(a) and the FDA's preemption regulation, 21 C.F.R. § 808.1(d)(1), and held that the state law at issue was not preempted because it was a law of general applicability. Medtronic dismisses this case on the ground that it did not involve a PMA device or a damages claim. Again, the factual assertions are correct but irrelevant. The Iowa Supreme Court's reading of *Lohr* and the applicable FDA regulation conflicts with the decisions in damages cases involving PMA devices, such as *Mitchell*, 126 F.3d at 912, and *Horn*, 376 F.3d at 174-75, that hold that section 360k(a) can preempt state-law claims of general applicability.

4. In Petitioners' view, the decision below is inconsistent with the text and purpose of the MDA, with FDA regulations, and with this Court's decision in *Lohr*. Medtronic